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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,763	02/21/2002	Jonathan A. Eppstein	19141.0016U2	4362

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/14/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,763

Applicant(s)

EPPSTEIN ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 32, 38, 39 and 49-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7, 8, 51, 55-57, 59, 60, 63, 64 is/are allowed, *except for the consideration of the interference issue.*
- 6) ☒ Claim(s) 1-6, 9, 10, 32, 38, 39, 49, 50, 52-54, 58, 61, 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed September 22, 2003. The Examiner acknowledges the amendments to the specification and to claims 1, 2, 5-10, 32, 38, 39, 49, 51, 52, 55-58 and 61-64. Claims 1-10, 32, 38, 39 and 49-64 are pending.

Drawings

2. The drawings were received on September 22, 2003. These drawings are approved by the Examiner.

Claim Objections

3. Claim 5 is objected to because of the following informalities: in line 5, --sample of biological-- apparently should be inserted before "fluid". Appropriate correction is required.

4. Claim 9 is objected to because of the following informalities: in line 11, --in the sample-- apparently should be inserted following "analyte". Appropriate correction is required.

5. Claim 38 is objected to because of the following informalities: in line 8, --the-- apparently should be inserted following "with". Appropriate correction is required.

6. Claim 52 is objected to because of the following informalities: in lines 19 and 21,

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--fluid-- apparently should be inserted following "biological". Appropriate correction is required.

7. Claim 62 is objected to because of the following informalities:

- a. In line 9, --the collected-- apparently should be inserted before "biological".
- b. In line 11, --the-- apparently should be inserted before "tissue".

Appropriate correction is required.

8. Claim 64 is objected to because of the following informalities: in line 15, "d)" apparently should read --(d)--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 6, 32, 39, 49, 52-54, 58, 61 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the "bottom layer" relates to the other elements of the invention. For example, one might assume that the bottom layer is disposed beneath the

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receiving layer, but if that were the case, it remains unclear how the receiving layer is capable of receiving a sample of biological fluid through the bottom layer.

Claim 32 recites the limitation "the final means" in line 3. There is insufficient antecedent basis for this limitation in the claim. There is no final means recited in claims 64 or 32 prior to this recitation.

Regarding claim 39, "(a)" (first occurrence) in line 2 and "(b)" (first occurrence) in line 3 render the claim indefinite because there are occurrences of "(a)" and "(b)" occurring in claims 38 and 39 that apparently represent different elements of the device of the claimed invention. One cannot be certain what "(a)" and "(b)" are intended to refer to.

Regarding claim 49, in line 2, "(a)" and "(d)" render the claim indefinite because the antecedent of "(a)" and "(d)" as set forth in claim 62 represent method steps, whereas "(a)" and "(d)" are used to represent structural elements in claim 49.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships involve how the "bottom layer" relates to the other elements of the invention. For example, one might assume that the bottom layer is disposed beneath the receiving layer, but if that were the case, it remains unclear how the receiving layer is capable of receiving a sample of biological fluid through the bottom layer.

Further regarding claim 52, "(A)" (first occurrence) in line 13 and "(B)" (first occurrence) in line 15 render the claim indefinite because there are occurrences of "(A)" and

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“(B)” occurring in lines 9 and 10 of the claim that represent different elements of the method of the claimed invention. One cannot be certain what “(A)” and “(B)” are intended to refer to.

Regarding claim 58, “(a)” (first occurrence) in line 2 and “(b)” (first occurrence) in line 4 render the claim indefinite because there are occurrences of “(a)” and “(b)” occurring in claim 57 that apparently represent different elements of the device of the claimed invention. One cannot be certain what “(a)” and “(b)” are intended to refer to.

Regarding claim 61, the limitation “the opening” is recited in line 10. This limitation renders the claim indefinite because it is unclear whether there is only one opening or if there can be more than one as indicated in line 5.

Regarding claim 62, the limitation “the hole” is recited in line 12. This limitation renders the claim indefinite because it is unclear whether there is only one hole or if there can be more than one as indicated in line 5.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 2, 3, 5, 6, 9, 38, 39, 49, 50, 52, 53, 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcia et al. (‘403). Garcia et al. teach a glucose medical monitoring system. The system detects the presence or determines the amount of an analyte (glucose) in a biological fluid (blood). An embodiment of the system includes a multi-layer integrated device

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602 comprising a receiving layer or pad **648** for receiving a sample of fluid and facilitating movement of the fluid; an analyte sensor **652** for detecting the presence or amount of the analyte in the fluid; a substrate layer **632** that is capable of being in contact with a processing circuit; and a bottom layer **634**. The receiving layer is located underneath at least a portion of the substrate layer and facilitates movement of the fluid to the sensor. The substrate layer can have at least one opening therein to allow an LED source **612** and photodiode sensor **614** access to the analyte sensor. The analyte sensor **652**, LED source **612** and photodiode sensor **614** form a detector that is capable of being in contact with a display. The bottom layer also has at least one opening therein to allow receiving layer or pad access to the fluid. A lancing unit **640** is provided to porate or form an opening in a skin surface. The receiving layer induces the flow of fluid from the opening and to the sensor by wicking although the wicking action may be replaced or assisted by vacuum, capillary action, or other flow or transport processes (col. 13, lines 26-31).

In operation, the first receiving layer or pad is positioned to contact tissue; the tissue is porated to form at least one hole therein; biological fluid is extracted from the opening and collected in the first layer; and the sensor is wetted by the fluid in order to measure a characteristic of the biological fluid. The extraction and movement of the fluid may be induced by negative pressures such as vacuum or capillary action or positive pressures such as the pressure that is inherently placed on the device when the lancing device is activated. An opening may be formed in the first layer as the opening is formed in the tissue (col. 15, lines 39-43).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1, 4 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. ('403) in view of Erickson et al. ('184). Garcia et al., as discussed hereinabove, teach all of the limitations of the claims except that the integrated fluid harvesting and analysis device is used with interstitial fluid. Erickson et al. teach that is known in the art that blood and interstitial fluid are interchangeable as biological fluids that can be analyzed to provide an indicator of analytes such as glucose within the body. Erickson et al. further teach that both blood and interstitial fluids can be collected using similar lancing and collection devices (col. 5, lines 34-41). It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that integrated devices similar to those taught by Garcia et al. could be used to collect interstitial fluids in view of the teachings of Erickson et al. as an alternative means to determine glucose levels within the body of a subject.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. ('403) in view of Mombrinie ('278). Garcia et al., as discussed hereinabove, teach all of the limitations of the claims except that the pad contains a surfactant to facilitate transport of the sample across the pad. Mombrinie teaches that is known in the art that surfactants may be added to wicking materials in order to enhance the wicking capability of the material (col. 4, line

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67 - col. 5, line 3. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to provide a pad similar to that taught by Garcia et al. with a surfactant in view of the teachings of Mombrinie in order to enhance the wicking capability of the material, thereby facilitating the transport of fluid across the pad.

Allowable Subject Matter

16. Claims 7, 8, 51, 55-57, 59, 60, 63 and 64 are allowable over the prior art of record except for the consideration of the interference issue.

17. Claim 32 and 58 would be allowable over the prior art of record, except for the consideration of the interference issue, if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Response to Arguments

18. Applicant's arguments, see pages 16-17 of the amendment filed September 22, 2003, with respect to the drawing objections; the objections to the specification and the claims; the rejections of claims 5-10, 32, 49, 52-54 and 61-64 under 35 USC 112, second paragraph; and the prior art rejections of claims 55 and 56 under 35 U.S.C. 103(a) have been fully considered and are persuasive. The drawing objections; the objections to the specification and the claims; the rejections of claims 5-10, 32, 49, 52-54 and 61-64 under 35 USC 112, second paragraph; and the prior art rejections of claims 55 and 56 under 35 U.S.C. 103(a) set forth in the Office Action mailed September 12, 2003 have been withdrawn. However, upon further consideration, new

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claim objections are made for claims 5, 9, 38, 52, 62 and 64 and new rejections under 35 USC 112, second paragraph, are made for claims 6, 32, 39, 49, 52-54, 61 and 62 hereinabove.

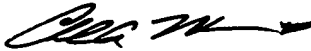
Applicant did not submit any arguments regarding the rejections of claims 2, 3, 5, 6, 9, 38, 39, 49, 50, 52, 53, 61 and 62 under 35 U.S.C. 102(b) and the rejections of claims 1, 4, 10 and 54 under 35 U.S.C. 103(a) made in the Office Action mailed September 12, 2003. As such, said rejections are maintained.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

cam
January 9, 2004